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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/551,494	04/18/2000	Frank Meulewaeter	021565-075	2755

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BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
EPPS, JANET L	
ART UNIT	**PAPER NUMBER**
1635	9

DATE MAILED: 12/14/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/551,494	MEULEWAETER ET AL.	
	Examiner	Art Unit	
	Janet L. Epps	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *1-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-38,42-49,53 and 54* is/are rejected.

7)☒ Claim(s) *39-41 and 50-52* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 12

WILLIAM N. PHILLIPS
PATENT ANALYST

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 32-52 in Paper No. #8 is acknowledged. The traversal is on the ground(s) that claims 5 to 13, and claims 22-31 includes all of the limitations of claim 32, the generic claim of Group II. This is not found persuasive because neither claim cited by Applicants in group I are directed to a method for introducing inhibitory RNA in the cytoplasm of plant cells as recited in the preamble of generic claim 32 of Group II. The method of Group II would produce a different result than that produced in the method embraced by Group I. The invention of Group I is directed to isolating nucleic acid with a specific function, however the invention of Group II is drawn to introducing inhibitory RNA into the cytoplasm of plant cells. The specification as filed teaches that "inhibitory RNA" are used to reduce or abolish gene expression. The method of Group I is not intended to produce the same results as that expected from practicing the method of Group II.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. #8.

Priority

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: Applicant's Declaration states that this application claims priority to application 09/294,022 under 35 USC§ 120, however this application was abandoned and re-filed as provisional application 60/219,314. Applicant's can

not claim benefit to a provisional application under 35 USC § 120, this claim must be made under 35 USC § 119(e).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 32, 34, 38, 42, 43, 45, 49, and 53-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Fitzmaurice et al.

Claim 32 recites a method for introducing inhibitory RNA in the cytoplasm of plant cells, comprising introducing into said plant cell a viral RNA vector comprising said inhibitory RNA or comprising a chimeric nucleic acid which produces the inhibitory RNA when transcribed, wherein said viral RNA vector is derived from satellite RNA virus; and introducing a corresponding helper virus into said plant cell. Claims 43-49 read on a kit for delivering inhibitory RNA in the cytoplasm of a plant cell, comprising a viral vector derived from a satellite RNA virus, said vector comprising a chimeric nucleic acid which when transcribed yields said inhibitory RNA or which comprises said inhibitory RNA, and a corresponding helper virus. The prior art is applied to the extent a single reference discloses all of the elements of the claimed kit and further discloses said elements for use in delivering inhibitory RNA to a plant cell.

Fitzmaurice et al. describe the satellite tobacco mosaic virus (STMV), recombinant STMV RNA molecules containing exogenous RNA segments, which are heterologous to naturally occurring STMV RNAs, and a recombinant expression system making possible

production of a desired gene product in the cytoplasm of a plant infected with recombinant STMV RNA molecules and a helper virus (page 1, lines 9-16). Fitzmaurice et al. also teach a method of transforming plant cells by introducing into cytoplasm of such cells infectious recombinant DNA molecules derived from STMV ssRNA, having such exogenous RNA segments, and a helper virus of STMV (page 1, lines 32-36). All of STMV's helper viruses are rod-shaped tomamoviruses, and includes tobacco mosaic virus (TMV), that is a prototype of the group (page 3, lines 13-16). The exogenous RNA segments of this reference includes those encoding different heterologous proteins, RNA having catalytic activity (i.e. ribozymes), regulator functions, and may also be anti-sense RNA (page 13, lines 14-37). The STMV-based transformation and expression system of Fitzmaurice et al. has a broad host range, including herbaceous plants such as solanceous plants, e.g. tobacco (member of *Nicotiana* spp.) , tomato, etc. (Page 15, lines 26-30)

Fitzmaurice et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

6. Claims 32, 34, 42, 43, 45, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Masuta et al.

Masuta et al. relates to a novel vector constructed by inserting an exogenous RNA fragment into a vector comprising a satellite RNA of a plant virus. These novel vectors may be effectively used for transformation of plant cells. The method for transforming a plant with the vectors of the present invention comprises simultaneously inoculating said plant with a recombinant RNA vector and helper virus to introduce an exogenous gene into cells of said plant, wherein said RNA vector comprises an exogenous gene integrated into the satellite RNA

(col. 3, lines 32-64). The satellite RNAs used in the invention of Masuta et al. are not limited to those derived from CMV, those having the same effect in spite of the difference in a partial base sequence fall within the invention (col. 2, lines 30-33).

Masuta et al. teach that the vectors of the present invention can be used to produce a virus-resistant plant by introducing the antisense sequence of a plant virus in the plant to transform it. (col. 4, lines 38-40). Furthermore, this reference teaches that antisense RNA against a virus or the like can be distributed to the whole plant body (col. 4, lines 60-64). In one particular embodiment, Masuta et al. teach the transformation of recombinant satellite RNA together with CMV into a leaf of tobacco (col. 7, lines 40-44).

Masuta et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 32-38, 42-49, and 53-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzmaurice et al., and Masuta et al. as applied above in view of Grierson et al.

The discussion of Fitzmaurice et al., and Masuta et al. set forth above is incorporated here. However, neither of the above references specifically teaches wherein the inhibitory RNA comprises an inverted repeat, nor do they teach wherein said inhibitory RNA comprises a complementary stretch of at least 50 or at least 100 nucleotides of sense and antisense RNA.

Grierson et al. teach constructs and methods for enhancing the inhibition of a target gene within an organism comprising inserting into the gene silencing vector an inverted repeat sequence of all or part of a polynucleotide region within the vector. The inverted repeat sequence may be a synthetic polynucleotide sequence or comprise a modified natural polynucleotide sequence. One a preferred embodiment, the gene silencing vectors of Grierson et al. comprises 5'-UTR inverted repeat sequences (antisense to naturally occurring 5'-UTR) positioned upstream of the coding sequence (i. e. sense sequence; see page 5, lines 1-30). Grierson et al. also teach that antisense regions useful in down regulation of a target gene are generally somewhere in the region of 50 nucleotides (page 1, lines 10-26). It is also noted that the teachings of Grierson et al. provide for constructs comprising multiple copies of the inverted repeat regions (antisense regions; see Figure 1B). Therefore, if there were two copies of the inverted repeat, the antisense region would be at least 100 nucleotides in length.

It would have been obvious to one of ordinary skill at the time of filing to modify the Fitzmaurice et al., and Masuta et al. references with the teachings of Grierson et al. in the design of the present invention, since Grierson et al. "have found that the inhibitory effect of a gene silencing vector can be enhanced by creating in the vector an inverted repeat of a part of the sequence of the vector (page 4, lines 24-26). One of ordinary skill in the art would have been motivated to modify the gene silencing constructs of Fitzmaurice et al., And Masuta et al. by incorporating one or more inverted repeats into these constructs since the teachings of Grierson et al. are clearly expected to have enhanced properties in comparison to unmodified constructs.

Therefore, the invention as a whole would have been prima facie obvious at the time of filing over Fitzmaurice et al., and Masuta et al. in view of Grierson et al.

Allowable Subject Matter

9. Claims 39-41 and 50-52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art searched does not teach or suggest a method or kit comprising chimeric viral gene silencing constructs wherein said construct is derived from satellite tobacco necrosis virus, comprises an origin of assembly of tobacco mosaic virus and wherein said helper virus is derived from tobacco necrosis virus.

As a point of interest it is noted that Wilson (WO 87/06261 A1) and Ahlquist et al. (US 5,627,060) teach recombinant or hybrid viral RNA constructs wherein the origin of assembly is from TMV and wherein heterologous viral sequences can be incorporated into said construct. However, each reference teaches wherein the coat protein is provided from the same virus that the origin of assembly is derived. The references do not teach that the viral source of the origin of assembly and coat protein can be isolated from different sources.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps
Examiner
Art Unit 1635
JLE
December 10, 2001

SEAN McGARRY
PRIMARY EXAMINER